UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Note to Reader

Background: As part of its effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), which is designed to ensure that the United States continues to have the safest and most abundant food supply. EPA is undertaking an effort to open public dockets on the organophosphate pesticides. These dockets will make available to all interested parties documents that were developed as part of the U.S. Environmental Protection Agency's process for making reregistration eligibility decisions and tolerance reassessments consistent with FQPA. The dockets include preliminary health assessments and, where available, ecological risk assessments conducted by EPA, rebuttals or corrections to the risk assessments submitted by chemical registrants, and the Agency's response to the registrants' submissions.

The analyses contained in this docket are preliminary in nature and represent the information available to EPA at the time they were prepared. Additional information may have been submitted to EPA which has not yet been incorporated into these analyses, and registrants or others may be developing relevant information. It's common and appropriate that new information and analyses will be used to revise and refine the evaluations contained in these dockets to make them more comprehensive and realistic. The Agency cautions against premature conclusions based on these preliminary assessments and against any use of information contained in these documents out of their full context. Throughout this process, If unacceptable risks are identified, EPA will act to reduce or eliminate the risks.

There is a 60 day comment period in which the public and all interested parties are invited to submit comments on the information in this docket. Comments should directly relate to this organophosphate and to the information and issues available in the information docket. Once the comment period closes, EPA will review all comments and revise the risk assessments, as necessary.

These preliminary risk assessments represent an early stage in the process by which EPA is evaluating the regulatory requirements applicable to existing pesticides. Through this opportunity for notice and comment, the Agency hopes to advance the openness and scientific soundness underpinning its decisions. This process is designed to assure that America continues to enjoy the safest and most abundant food supply. Through implementation of EPA's tolerance reassessment program under the Food Quality Protection Act, the food supply will become even safer. Leading health experts recommend that all people eat a wide variety of foods, including at least five servings of fruits and vegetables a day.

Note: This sheet is provided to help the reader understand how refined and developed the pesticide file is as of the date prepared, what if any changes have occurred recently, and what new information, if any, is expected to be included in the analysis before decisions are made. **It is not meant to be a summary of all current information regarding the chemical.** Rather, the sheet provides some context to better understand the substantive material in the docket (RED chapters, registrant rebuttals, Agency responses to rebuttals, etc.) for this pesticide.

Further, in some cases, differences may be noted between the RED chapters and the Agency's comprehensive reports on the hazard identification information and safety factors for all organophosphates. In these cases, information in the comprehensive reports is the most current and will, barring the submission of more data that the Agency finds useful, be used in the risk assessments.

Jack E. Housenger, Acting Director
Special Review and Reregistration Division

01-JUN-1999

MEMORANDUM

SUBJECT: ***COUMAPHOS*** **-** Report of the FQPA Safety Factor Committee

The FQPA safety factor recommendation in this report supercedes that previously reported for coumaphos in the FQPA SAFETY FACTOR RECOMMENDATIONS FOR THE ORGANOPHOSPHATES dated August 6, 1998.

FROM: Brenda Tarplee, Executive Secretary
FQPA Safety Factor Committee
Health Effects Division (7509C)

THROUGH: Ed Zager, Chairman
FQPA Safety Factor Committee
Health Effects Division (7509C)

TO: Christina Jarvis, Risk Assessor
Reregistration Branch 2
Health Effects Division (7509C)

PC Code: 036501

The FQPA Safety Factor Committee met on May 17, 1999 to reevaluate the hazard and exposure data for coumaphos, and recommended that the FQPA Safety Factor (as required by Food Quality Protection Act of August 3, 1996) be removed (1x) in assessing the risk posed by this chemical. The FQPA safety factor recommendation in this report supercedes that previously reported for coumaphos in the *FQPA SAFETY FACTOR RECOMMENDATIONS FOR THE ORGANOPHOSPHATES* dated August 6, 1998.

1. HAZARD ASSESSMENT

a. Adequacy of the Toxicology Database

On May 11, 1999, the HIARC reviewed the recently submitted acute and subchronic neurotoxicity studies with coumaphos in rats, which were previously identified as data gaps. The HIARC determined that these studies were acceptable and therefore, the toxicology database is now adequate for coumaphos according to the Subdivision F Guideline requirements for a food-use chemical.

b. Determination of Susceptibility

Prenatal developmental toxicity studies in rats and rabbits provided no indication of increased susceptibility of rat or rabbit fetuses to *in utero* exposure to coumaphos. There was no indication of increased susceptibility in the offspring as compared to parental animals in the 2-generation reproduction study. In these studies, effects in the fetuses/offspring were observed only at or above treatment levels which resulted in evidence of parental toxicity.

c. Determination of Need For Developmental Neurotoxicity Study

There are sufficient data available to adequately assess the potential for toxicity to young animals following pre-and/or post-natal exposure to coumaphos. These include acceptable developmental toxicity studies in rats and rabbits, as well as, a 2-generation reproduction studies in rats. In addition, no treatment-related neuropathology was seen after acute and subchronic exposure to rats. Additionally, there was no evidence of abnormalities to the fetus to the fetal nervous system in the pre- and post-natal studies. Based on the weight-of-evidence, the HIARC determined that a developmental neurotoxicity study in rats is not required for coumaphos.

2. EXPOSURE ASSESSMENTS

a. Dietary Food Exposure Considerations

Coumaphos is not registered for use on crops. Coumaphos is used as an insecticide for external (dermal) treatment of arthropod-type pests on cattle, goats, horses, sheep, and swine. Permanent tolerances have been established for the combined residues of coumaphos and its oxygen analog in milk, eggs, and the meat, fat, and meat byproducts of cattle, goats, hogs, horses, poultry, and sheep at levels ranging from 0.5 ppm to 1 ppm (40 CFR §180.189). Although tolerances are still listed for poultry and eggs, the use of coumaphos on poultry (eggs) has been canceled.

Residues of coumaphos will transfer to meat and milk (tolerances are established) which are foods considered to be highly consumed by infants and children (1993 NAS report, Pesticides in the Diets of Infants and Children).

USDA Food Safety and Inspection Service (FSIS) monitoring data (1993-1997) show that residues of coumaphos are found in beef fat, horse fat, and veal fat. In some cases, the residue levels (1.06 - 1.62 ppm) exceeded the established tolerance level (1 ppm). The majority of samples analyzed, however, showed no detectable levels of coumaphos: 4 detects out of 4,500 beef fat samples (2 of which were above tolerance); 14 detects out of 2,063 horse fat samples (4 of which were above tolerance) [Responses to the FQPA SFC SOP questions for the OP Marathon provided by S. DeVito, May 27, 1998].

The concern for these tolerance violations were allayed by the findings that residues of coumaphos would be expected to be reduced or removed through normal preparation or processing, such as cooking meats or milk pasteurization (*Memorandum*: S. DeVito to M. Rice dated November 23, 1998). However, these tolerance violations should be addressed in the tolerance reassessment.

Dietary food exposure analyses were performed to estimate the dietary risk resulting from the dermal animal application of coumaphos. Both the acute and chronic dietary food exposure analyses were refined using anticipated residue levels calculated from field trial data. By incorporating anticipated residue data, these analyses reflect a more realistic picture of the acute and chronic dietary food risk associated with coumaphos but do not underestimate the potential exposure.

b. Drinking Water Exposure Considerations

A drinking water exposure assessment had not been conducted for coumaphos at the time of this meeting. Since the only registered use for coumaphos is dermal applications to animals, drinking water contamination is unlikely.

c. Residential Exposure Considerations

Coumaphos is not currently registered for residential use.

3. SAFETY FACTOR RECOMMENDATION AND RATIONALE

a. Recommendation of the Factor

Previously for coumaphos, the FQPA safety factor recommendation was 3x due to the data gaps for the acute and subchronic neurotoxicity studies (*FQPA Safety Factor Recommendations for the Organophosphates* dated August 6, 1998). Now that these data requirements have been satisfied, the Committee recommended that the FQPA safety factor be **removed (1x)**.

b. Rationale for Removing the FQPA Safety Factor

The Committee concluded that the safety factor could be removed for coumaphos because:

i. The toxicology database is now complete (previous data gap has been satisfied).

ii. There is no indication of increased susceptibility of rat or rabbits to coumaphos. In the developmental and reproduction toxicity studies, effects in the fetuses/offspring were observed only at or above treatment levels which resulted in evidence of parental toxicity.

iii. The HIARC determined that a developmental neurotoxicity study in rats is not required..

iv. The dietary food exposure assessment does not underestimate the potential exposure for infants and children from residues in food. No exposure is expected to infants and children from drinking water or residential sources.

FQPA SAFETY FACTOR COMMITTEE MEETING

17MAY1999

COUMAPHOS (Revisit)

Name	Division/Branch
[illegible]	HED
[illegible]	HED
[illegible]	HED
Jon Fleuchaus	OGC
[illegible]	HED
[illegible]	EFED
Daniel Rieder	EFED
[illegible]	HED
Rick Keigwin	RD

FQPA SAFETY FACTOR COMMITTEE MEETING

24MAY1999

COUMAPHOS (Revisit)

Name	Division/Branch
[illegible]	EFED/
[illegible]	HED
[illegible]	HED
[illegible]	HED
[illegible]	EGC
[illegible]	RD
[illegible]	HED/TOXI
[illegible]	HED
[illegible]	RCAB